REMARKS

I. Status of the Application

Claims 1-51 are presently pending in the application. Claims 14-25 and 27-51 have been withdrawn from consideration. Claims 14-19 and 23 have been cancelled without prejudice to the filing of any appropriate continuation application, as being directed to non-elected subject matter. New claims 52-55 have been added. Applicants gratefully acknowledge that the previous rejection of claims 1, 2, 7-13 and 26 under 35 U.S.C. § 112, second paragraph, as being indefinite, has been withdrawn. Claims 1, 2-13 and 26 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 1, 3-13 and 26 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Claims 1, 3, 5-13 and 26 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Walker et al., WO 2002/018575. Claims 1, 3, 5-8 and 26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Zhao et al. (1998) *Genomics* 53:184.

Applicants have amended the claims under consideration to more clearly define and distinctly characterize Applicants' novel invention. Specifically, Applicants have amended claims 1 and 3 to recite 80% sequence homology. Support for these amendments can be found at least at pages 13 and 14 of the instant specification, where Applicants teach % homologies for nucleic acid and amino acid sequences. Support for the amendment to claim 7 to recite hybridizes 'under stringent conditions' can be found in the specification at least at page 15, where Applicants teach conditions for hybridizing nucleic acid sequences. Support for new claims 52-55 can be found throughout the specification and the claims as originally filed, as well as in amended claims 1 and 3.

The amendments presented herein contain no new matter. Applicants respectfully request entry and consideration of the foregoing amendments, which are intended to place the case in condition for allowance.

II. The Specification Provides Adequate Written Description for the Pending Claims

At page 6 of the instant Office Action, claims 1-13 and 26 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement for containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office Action asserts that to satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of compositions or methods, it must be clear that: (1) the identifying characteristics of the claimed compositions or methods have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed. Applicants traverse this rejection.

The Office Action asserts that, with regard to claim 4, "the recitation of "a nucleotide sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6," can be interpreted [as] any nucleotide sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6, including any fragment thereof. However, the specification lacks support for any polynucleotide fragments of SEQ ID NOs: 4-6 ***having the desired biological function***" (page 10, emphasis added).

Applicants disagree. Claim 4 recites, "An isolated nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6." This claim **does not recite *fragments*** of SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6. A nucleic acid molecule embraced by this claim would include the sequence of SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6. A fragment ***would not be equivalent*** to SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6. Furthermore, claim 4 does ***not require*** a ***biological*** function. Accordingly, the Office Action is ascribing limitations to the claim that are ***simply not there***.

There may be variability among the species of nucleic acid molecules encompassed by the scope of claim 4 because SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6 may be combined with other sequences, however the scope of the genus is defined by the presence of the structure shown in SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6. Thus, all members of the genus will predictably include SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6.

The instant specification provides an actual reduction to practice and teaches the complete structure of three species within the genus; i.e., the cDNA sequences shown in SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6 (see, e.g., page 12 and Figures 13-15 of the instant specification). SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6 also represent a partial structure of each nucleic acid molecule encompassed by the claimed genus: each member of the claimed genus must include SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6 as part of its structure because the presence of SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6 defines the scope of the claimed genus.

The Examiner's attention is respectfully directed to pages 13 and 14 of the *Written Description Training Materials*, which states that the "specification ***satisfies the written***

description requirement...with respect to the claimed DNAs" and that the claim referred to recites, "An isolated DNA ***comprising*** SEQ ID NO:16." The Training Materials go on to state,

> Because ***SEQ ID NO:16*** is a ***structural feature common to all members of the genus*** and the specification describes the complete structure (sequence) of SEQ ID NO:16, one skilled in the art would recognize that the applicant was ***in possession of a common structural feature of members of the genus***. The species shown in the specification, i.e., SEQ ID NO:16, is therefore representative of the species within the claimed genus. (*Written Description Training Materials*, Revision 1, March 25, 2008, emphasis added).

For at least these reasons, the specification provides adequate written description for claim 4.

New claim 54 depends from claim 4 and, accordingly, is limited to specific nucleic acid sequences. Similarly, new claim 55 is directed in part to specific protein sequences, i.e., a nucleic acid molecule which encodes a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3. As discussed for claim 4 above, the scope of the genera are defined by the presence of the structure shown in SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6 (claim 54) or SEQ ID NO: 1, SEQ ID NO:2 and SEQ ID NO:3 (claim 55). Thus, all members of these genera will predictably include SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6, or SEQ ID NO: 1, SEQ ID NO:2 and SEQ ID NO:3. Accordingly, Applicants submit that the specification provides adequate support for claims 54 and 55.

New claim 52 recites, "An isolated nucleic acid molecule from a eukaryotic cell comprising a nucleotide sequence having at least about ***85% sequence homology*** to a nucleotide sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6." New claim 53 recites, "An isolated nucleic acid molecule from a eukaryotic cell comprising a nucleic acid molecule which encodes a polypeptide comprising an amino acid sequence having at least about ***85% sequence homology*** to an amino acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3."

The recitation of a nucleotide sequence or amino acid sequence having at least about 85% sequence homology represents a partial structure. That is, at least 85% of the nucleic acids in the sequence will match those of SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6, and at least 85% of the amino acids in the sequence will match those of SEQ ID NO:1, SEQ ID NO:2 or SEQ ID NO:3. The disclosure of SEQ ID NOs:1, 2, 3, 4, 5 and 6 combined with the pre-existing knowledge in the art regarding the genetic code would have put one of skill in the art in possession of the genus of nucleic acids that encode SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6, and the genus of amino acids that encode SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3 (See *Written Description Training Materials*, Revision 1, March 25, 2008, pages 37 and 38). Thus, the instant specification provides adequate written description for claims 52 and 53.

Amended claims 1 and 3 and claims depending therefrom recite an amino acid sequence or nucleic acid molecule, respectively, having 80% sequence homology to SEQ ID NO:1, SEQ ID NO:2 or SEQ ID NO:3 (claim 1) or 80% sequence homology to SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6 (claim 3). Claims 5 and 6 and claims depending therefrom recite nucleic acid molecule or amino acid sequence, respectively, having 85% sequence homology to SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6 (claim 5) or 80% sequence homology to SEQ ID NO:1, SEQ ID NO:2 or SEQ ID NO:3 (claim 6). As discussed above, the recitation of a nucleotide sequence or amino acid sequence having at least about 85% (or at least about 80%) sequence homology represents a partial structure. Accordingly, the specification provides adequate written description for claims 1, 3, 5 and 6 and claims depending therefrom.

For at least these reasons, the specification provides adequate written description for the pending claims. Accordingly, Applicants request that the rejection of claims 1-13 and 26 under

35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement be reconsidered and withdrawn.

III. The Pending Claims Are Enabled

At page 8 of the instant Office Action, claims 1-13 and 26 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. The Office Action asserts that the specification does not enable any person skilled in the art to which it pertains, or to which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants traverse this rejection.

35 U.S.C. § 112, first paragraph requires that the specification must enable a person skilled in the art to make and use the claimed invention. However, a specification need not, and should not, disclose what is well known in the art. The invention that one skilled in the art must be enabled to make and use is that defined by the claims of the particular application. The issue of adequate enablement depends on whether one skilled in the art could practice the claimed invention without undue experimentation. Enablement is not precluded by the necessity of some experimentation such as routine screening, even if it is extensive routine screening. Also, the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation (MPEP 2164.01) if the level of skill in the art is high or if all of the methods needed to practice the claimed invention are well known. *In re Wands*, 8 U.S.P.Q. 2d 1400, 1406 (Fed. Cir. 1988).

> The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. (Citations omitted). The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a

reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 8 U.S.P.Q. 2d at 1404.

Applicants respectfully submit that the instant specification provides ample direction and guidance to make and use an isolated nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6 as well as to make and use an isolated nucleotide sequence containing 80% or 85% sequence homology to SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6. Applicants respectfully submit that the instant specification provides ample direction and guidance to make and use an amino acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3 as well as to make and use an amino acid sequence containing 80% or 85% sequence homology to SEQ ID NO:1, SEQ ID NO:2 or SEQ ID NO:3. Applicants provide the nucleotide sequence for each of SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6, and provide the amino acid sequences for each of SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3.

In view of the sequence information that Applicants provide and in view of the knowledge and skill of one of ordinary skill in the art at the time of filing, determining whether a nucleic acid molecule includes a sequence set forth as SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6 or a sequence having 80% or 85% sequence homology thereto would involve only ***routine screening*** using techniques that were ***well known*** in the art at the time of filing. Similarly, determining whether an amino acid sequence includes a sequence set forth as SEQ ID NO:1, SEQ ID NO:2 or SEQ ID NO:3 or a sequence having 80% or 85% sequence homology thereto would involve only ***routine screening*** using techniques that were ***well known*** in the art at the time of filing.

Applicants teach that particular nucleic acid sequences can be identified in a sample using a variety of art-known methods such as, for example, using a probe/primer in a PCR

reaction (page 48 of the specification), high density arrays (page 49 of the specification), and direct sequencing methods (page 50 of the specification). One of skill in the art could easily ascertain whether a nucleic acid molecule or amino acid sequence has a specific percent homology, and there are many computer programs publicly available to do so (e.g., NCBI BLAST and the like). Thus, one of skill in the art could easily ascertain nucleic acid and/or amino acid sequences.

The Office Action asserts that, with regard to claim 4, "the recitation of "a nucleotide sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6," can be interpreted [as] any nucleotide sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6, ***including any fragment thereof***. However, the specification lacks support for any polynucleotide fragments of SEQ ID NOs: 4-6 ***having the desired biological function***" (page 10, emphasis added).

As discussed in Section II above, claim 4 recites, "An isolated nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6." Claim 4 **does not recite *fragments*** of SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6, and does ***not require*** a ***biological*** function. The Office Action is ascribing limitations to the claim that are ***simply not there***.

For at least these reasons, the application as a whole provides adequate enablement for the pending claims. Accordingly, Applicants request that the rejection of claims 1-13 and 26 under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement be reconsidered and withdrawn.

IV. Claims 1, 5-13 and 26 Are Novel Over Walker et al.

At page 8 of the instant Office Action, claims 1, 5-13 and 26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Walker et al., WO 2002/018575. Applicants traverse this rejection. Applicants respectfully submit that for a reference to anticipate a claim, the reference must teach each and every element of the claim.

Walker et al. fails to teach or suggest the claimed nucleic acid molecules. The Office Action admits that Walker et al. did not physically clone SEQ ID NO:3 from chromosomal DNA. The Office Action then goes on to assert that expression and characterization of its encoded protein sequence was previously published as evidences of page 19 of Walker et al. under CDC23. Applicants disagree.

Nowhere does Walker et al. teach or suggest the claimed isolated nucleic acid sequences encoding polypeptides having the claimed activities. Furthermore, Walker et al. fails to teach or suggest that SEQ ID NO:3 encodes ***any polypeptide***, let alone a polypeptide having at least 80% or 85% sequence homology to SEQ ID NO:2 and/or one or more Tome-1 activities. Although Walker et al. teaches SEQ ID NO:3, Walker et al. does ***not*** teach or suggest that SEQ ID NO:3 encodes CDC23, as asserted by the Office Action, and the Office Action has provided no evidence that this is so. Furthermore, Walker et al. teaches that SEQ ID NO:3 is ***coexpressed with*** the ***CDC23 cDNA***: "Column 1 is the SEQ ID number, column 2, the ***known cell cycle gene(s) with which the cDNA is most highly co-expressed***..." (page 8, lines 13-16, emphasis added). This evidences that CDC23 cDNA and the cDNA set forth as SEQ ID NO:3 are different. In addition, Applicants submit that Zhao et al. provides evidence that the cDNA sequence set forth in Figure 1 of Zhao et al. ***is not the same sequence*** as that set forth as SEQ ID NO:3 of Walker et al. In this regard, the Office Action has provided no evidence supporting the

assertion that the sequences are the same (e.g., a sequence alignment of the cDNA of Zhao et al. and SEQ ID NO:3 of Walker et al.).

For at least these reasons, Walker et al. fails to anticipate the pending claims. Accordingly, Applicants request that the rejection of claims 1, 5-13 and 26 under 35 U.S.C. § 102(b) as being anticipated by Walker et al. be reconsidered and withdrawn.

V. Claims 1, 3, 5-8, 10 and 26 Are Novel Over Zhao et al.

At page 11 of the instant Office Action, claims 1-3, 5-8, 10 and 26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Zhao et al. (1998) *Genomics* 53:184. Applicants traverse this rejection. Applicants respectfully submit that for a reference to anticipate a claim, the reference must teach each and every element of the claim.

Zhao et al. fails to teach or suggest Applicants' claimed sequences. Zhao et al. is directed to the cloning and mapping of the human CDC23 gene. The human cDNA and its predicted amino acid sequences are listed in Figure 1. The Office Action asserts that the isolated cDNA of Zhao et al. as shown in figure 1 has 97% sequence homology to Applicants' SEQ ID NO:5, and encodes an amino acid sequence having at least 60% sequence homology to Applicants SEQ ID NO:2, yet the Office Action has provided ***no evidence*** that this is so. The Office Action states that an alignment was not provided because the nucleic acid sequence of Walker et al. is identical with that of Zhao et al. Applicants disagree. SEQ ID NO:3 of Walker et al. is not identical to the nucleotide sequence set forth in Figure 1 of Zhao et al. Furthermore, when Applicants used BLAST to compare the nucleotide sequence in Figure 1 of Zhao et al. to Applicants' SEQ ID NO:5 or the amino acid sequence in Figure 1 of Zhao et al. to Applicants' SEQ ID NO:2, Applicants obtained results stating that "no significant similarity is found". In

fact, the sequences set forth in Figure 1 of Zhao et al. fail to anticipate ***any*** of the claimed sequences. Thus, Zhao et al. fails to teach or suggest Applicants' claimed invention.

Accordingly, Applicants request that the rejection of claims 1-3, 5-8, 10 and 26 under 35 U.S.C. § 102(b) as being anticipated by Zhao et al. be reconsidered and withdrawn.

VI. CONCLUSION

Having addressed all outstanding issues, Applicants respectfully request reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

The Commissioner is authorized to apply any additional charges or any credits to our Deposit Account No. 19-0733.

Respectfully submitted,

Dated: September 15, 2008

By _____

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